



JUN 23 2003

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Charles Van Horn
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Washington DC 20005-3315

Re: Patent Term Extension
Application for
U.S. Patent No. 4,758,579

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,758,579, which claims the human drug product Protonix® (pantoprazole sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of July 16, 2002 (67 Fed. Reg. 46681). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,818 - 0) + 583 \\ &= 1,992 \text{ days (5.5 years)}\end{aligned}$$

Since the regulatory review period began October 13, 1990, after the patent issued (July 19, 1988), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,758,579
Granted: July 19, 1988
Applicant: Kohl, et al.
Owner of Record: ALTANA PHARMA AG¹
Title: Fluoroalkoxy Substituted Benzimidazoles Useful as
Gastric Acid Secretion Inhibitors
Classification: 514/338
Product Trade Name: Protonix® (pantoprazole sodium)
Term Extended: 5 years

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext. By FAX: (703) 872-9411
Commissioner for Patents Attn: Karin Ferriter
P.O. Box 1450
Alexandria, VA 22313-1450

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin L. Ferriter
Senior Legal Advisor, Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read RE: Protonix® (pantoprazole sodium)
Acting Director Health Assessment Policy Staff, CDER FDA Docket No.: 00E-1348
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

¹A change of name was recorded at Reel 013128, Frame 0431 on August 7, 2002.
Applicant's name was changed from BYK Gulden Lomberg Chemische Fabrik GmbH to
ALTANA PHARMA AG. Note the attachment.